

REMARKS

By way of summary, Claims 1-15 and 17-25 and 27-35 were pending in this application prior to this Response. In the outstanding Office Action of April 30, 2009, Claims 1-15, 17-25 and 28-32 are rejected under 35 U.S.C. § 103(a) as unpatentable over Chanduszko (U.S. Publ. 2005/0059984) in view of Johnson (US 6,485,504). Claims 27 and 33-35 are rejected under 35 U.S.C. § 103(a) as unpatentable over Chanduszko in view of Johnson in further view of Kay (U.S. 5,662,683).

I. § 103(a) Claim Rejections

A. All Claim Rejections Fail to Provide Proper *Graham* Factual Inquiries and Fail to Articulate Findings under the KSR Examination Guidelines

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* ("Examination Guidelines"), which were published in the Federal Register Vol. 72, No. 195 (Docket PTO-P-2007-0031) on October 10, 2007, apply the Supreme Court's decision in *KSR Int'l. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) with regard to the issue of obviousness under 35 U.S.C. § 103(a) in relation to prior art. Applicant submits that the outstanding Office Action fails to satisfy the Examiner's burden in establishing an obviousness rejection.

Under the Examination Guidelines, and as reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

The Examination Guidelines confirms the role of Patent Office personnel as fact finders:

When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

72 Fed. Reg. 57527 (Oct. 10, 2007).

The Examination Guidelines further provide that “Once the Graham factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.” *Id.* “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 57528-57529 (internal citations omitted). Under the Examination Guidelines, a rejection must offer specific support for the following rationales Examiners may use to show obviousness:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Id. at 57529.

The April 30, 2009 Office Action fails to set forth the level of ordinary skill in the pertinent art, or who qualifies as one of ordinary skill in the field. Applicant submits that without such a finding, the Examiner’s combinations are improper, as the Examiner has not established that the references proposed by the combinations would be known to one of ordinary skill in the art, nor that one of ordinary skill would have the requisite knowledge and ability to make the desired combinations.

Moreover, the Examiner has failed to articulate specific rationales for the proposed combinations of references, and has failed to provide explicit explanations supporting the obviousness rejections. The Examiner summarily concludes that “[i]t would have been obvious

to one of ordinary skill in the art at the time of invention to modify Chanduszko et al. by having coil anchors with a distal end of the coil being releasably engaged to the distal end of the elongate body, as taught by Johnson et al., in order to effectively narrow the coil in diameter to facilitate deployment and also to minimize damage to tissue and allow flexibility and movement by the patient without disturbing the healing process." Office Action at 4. Similarly, the Office Action states: "[i]t would have been obvious to one of ordinary skill in the art to modify the loading portion of Chanduszko et al. to accommodate multiple anchors or coils in order to further secure the septum primum and septum secundum together." Office Action at 4. These are conclusory statements regarding the combinability of the cited prior art references; the Examiner has not (1) identified the knowledge one skilled in the art would possess, (2) described what modifications the skilled person would need to make to combine the prior art references, or (3) discussed whether that skilled person would have a reasonable expectation of success. Accordingly, Applicant submits that the Examiner's obviousness rejections are improper. More specific details relating to these missing inquiries and missing articulated findings are discussed in more detail below, along with Applicant's reasoned statements explaining why Applicant's claims are nonobvious over the cited art.

B. Independent Claims 1, 12, 20, and 31 Are Not Rendered Obvious over Chanduszko (U.S. Pub. No. 2005/0059984) in view of Johnson (U.S. 6,485,504)

The outstanding Office Action rejected independent Claims 1, 12, 20, and 31 under 35 U.S.C. §103(a) as being unpatentable over Chanduszko in view of Johnson. As explained in detail below, Applicant asserts that the claimed inventions recited in Claims 1, 12, 20, and 31 are not obvious because: (1) modifying Chanduszko with Johnson in the manner suggested by the Examiner would render the Chanduszko invention inoperable; (2) Johnson is in a different field of endeavor, and is not an analogous invention and thus is an inappropriate § 103(a) reference; and (3) even assuming that Johnson and Chanduszko are properly combinable, the resulting combination does not teach or suggest all elements of the claimed invention.

1. Chanduszko and Johnson Are Not Properly Combinable

Section 2143.01.V of the M.P.E.P. instructs that a proposed modification of a prior art reference in view of another reference cannot render the modified invention incapable of

performing its intended purpose.¹ Because the modifications to Chanduszko in view of Johnson as suggested by the Examiner would render Chanduszko inoperable for closing a PFO, a person having ordinary skill in the PFO art would not have modified Chanduszko in view of Johnson, as there would be no reasonable expectation of success. The combination is therefore an improper basis for an obviousness rejection.

Chanduszko discloses a device for delivering a suturing device 108, as shown in Chanduszko's Figures 2 and 5:

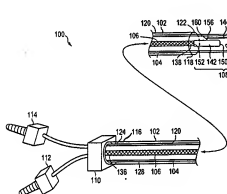


FIG. 2

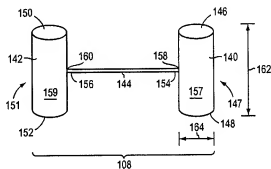


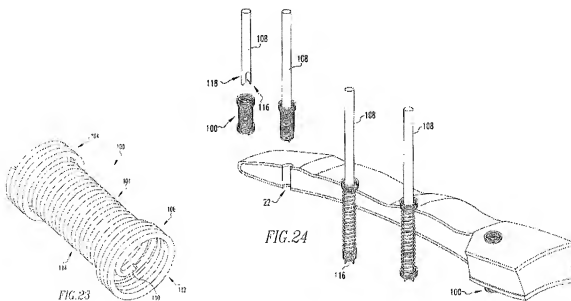
FIG. 5

The Office Action states Chanduszko "has an opening 132 near its distal end, and a loading portion or collar 106 [which Chanduszko calls a delivery member 106] releasably engages a proximal end 142 of the anchor after the anchor is advanced through the patent foramen ovale." Office Action at page 3. Chanduszko describes this structure at [0043]: "Referring still to FIG. 2, in one embodiment, the delivery member 106 and the suturing device 108 are initially **disposed within the lumen 130 of the elongate member 104.**" In order for Chanduszko to function properly, Chanduszko's suture device 108 is delivered on the inside lumen 130 of its elongate member 104 and is held in place by a delivery member 106 that is slideably moveable within the lumen 130. Chanduszko's implanted suture device 108 is only temporarily engaged with the delivery member 106 at the suture device's 108 proximal end (a second tissue engaging member

¹ M.P.E.P. § 2143.01.V ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."); *see also, id.* at 2143.01.VI ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

142), leaving the distal end (first tissue engaging member 140) free to slide out of the opening 132. If Chanduszko's suturing device 108 were located on the outside of the elongate member 104, it would not be connected to the delivery member 106 disposed inside the lumen 130. In order for Chanduszko to function properly its delivery member 106 and suturing device 108 must remain within the lumen 130, with the delivery member 106 engaged with only the proximal second tissue engaging member 142.

In contrast, Johnson discloses the use of a pushing rod 108 with a diameter less than its grommet 100, the pushing rod having a slot 116 that engages a single grommet 100 disposed on the outside of the rod 108 for placement through a hole 22 in bone, as reflected in Johnson's figures:



Johnson discloses no lumen in the pushing rod. Rather, the pushing rod engages only the distal end of the grommet 100, relying on a hard bony surface to hold the proximal end of grommet 100 (head flange 104 having a diameter greater than the diameter of the hole 22 in the bone) in place as it stretches the grommet 100 through a hole 22 in the bone. Because only Johnson's distal end engages the pushing rod 108, the head flange 104 is allowed to rotate freely with respect to the pushing rod 108 while it engages the hard bone surface outside the hole 22.

This approach and structure is incompatible with Chanduszko. If the suturing device 108 of Chanduszko is placed on the outside of the pushing rod 108 as with Johnson, it is impossible

for it to function with a “delivery member 106 [that] releasably engages a proximal end 142 of the anchor after the anchor is advanced through the patent foramen ovale” as the Office Action characterizes at pages 3-4. However, this is the modification the Examiner suggests: “Chanduszko et al. discloses the claimed invention except for the anchor being a coil having a distal end that releasably engages the opening in the elongate body near its distal end and axially elongating and radially reducing the coil by moving and rotating the piecing [sic] structure distal end relative to the loading collar, wherein the coil axially contracts to pinch the septum primum and the septum secundum together.”

The Office Action then inappropriately characterizes Johnson as addressing all these deficiencies of Chanduszko. However, as discussed above, only the distal end of Johnson's implant is releasably engaged to the pushing rod 108, leaving the proximal end of Johnson's implant to frictionally engage a hard bone surface at a bone hole 22 so it can rotate freely with respect to the pushing rod 108 during delivery. Johnson describes: “Once the slot 116 grasps the end of the spring 101, **the pushing rod 108 is twisted while the head flange 104 of the grommet 100 is held**, causing the tail flange 106 and the central portion 114 to narrow in diameter as the length of the grommet 100 extends under the twisting action.” Johnson col. 19 lines 16-20. Contrary to the Examiner's assertions, Johnson provides no structure that would releasably engage the proximal end of the grommet to axially elongate and radially reduce the grommet to enable delivery into a PFO as disclosed in Chanduszko. Rather, Johnson relies on contact between the proximal end of the grommet and the hard bone surface to cause the grommet to axially elongate and radially reduce. Use of such a system with the fragile tissue of the PFO as disclosed in Chanduszko would likely cause damage to the PFO tissue and be incapable of achieving the forces required to axially elongate and radially reduce the grommet for delivery.

For these reasons, Applicant submits that the Examiner's obviousness rejection over Chanduszko in view of Johnson is improper, and the rejections of the claims based on this combination be withdrawn.

2. Johnson is in a Different Field of Endeavor And Not An Analogous Invention

Typically a reference forming the basis of a § 103(a) obviousness rejection comes from the Applicant's field of endeavor. Although it is permissible to cite to a reference outside the

Applicant's field, the Examination Guidelines teach that when doing so "office personnel must . . . articulate" that the field different from the Applicant's "included a similar or analogous device (method, or product)." 72 Fed. Reg. at 57533. Because Johnson comes from a different field of endeavor than the Applicant's, and because Johnson does not include an analogous method, a § 103 rejection based on Johnson is improper.

Johnson discloses an invention belonging to a different field of endeavor: "an apparatus for holding a first portion of bone and a second portion of bone together for the bone to heal." Johnson at col. 1, ll. 40-42. The material properties of bone, for example density and durability, are significantly different than the soft tissue forming a heart septum. Because of the radical differences in the material properties of bone and heart septa, a person having ordinary skill in the PFO art would not look to the field of Johnson when trying to solve the problem of closing a PFO. Although Johnson states that the invention involves "the closure of hard or soft tissue," Johnson at col. 1, ll. 5-10, the term "tissue" is explicitly limited in the Johnson specification: "[t]issue is defined as bone, muscle or fascia that has been divided to gain access the [sic] *thoracic cavity, mediastinum, or abdomen.*" Johnson at col. 1, ll. 12-17. Because heart tissue is not something that is "divided to gain access" to one of the defined bodily areas, it is excluded by this definition; the necessary conclusion is that Johnson is a different field of endeavor.

Given that Johnson is in a different field of endeavor, in order for the reference to properly form the basis of a § 103(a) rejection it must be that the disclosed method is analogous to the Applicant's. 72 Fed. Reg. at 57533. The Examiner has not shown that the methods are analogous, and more importantly, they are not analogous. The method of Johnson involves using a coil ("grommet") 100 to line the interior of a hole or channel drilled in a bone. The coil in Johnson is functionally a sleeve, Johnson at col. 1, ll. 54-65, that is inserted into a channel drilled in a bone after which a suture is inserted through the sleeve. The method of using the radially expanding properties of coil to secure a sleeve inside a bone channel in Johnson is not analogous to a method of deploying a suturing device 108 through a lumen 130 for placement to pinch together two flaps of heart tissue. In the former, the coil could be substituted for any sleeve capable of adhering with the sides of a channel in a bone regardless of whether it axially expands or contracts, whereas such a tubular shaped sleeve—without more—would not be successful in pinching shut a PFO.

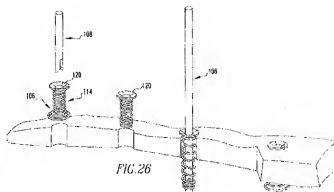
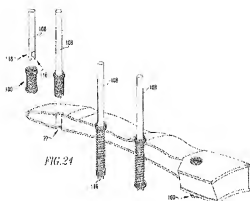
Moreover, based on the significant differences between the method described by Johnson and the method described by Chanduszko as discussed above, one of ordinary skill in the art would not have found it predictable to make the modifications proposed by the Examiner. For these additional reasons, a § 103(a) rejection based on Johnson is inappropriate.

3. Additional Features Are Not Taught or Suggested by Chanduszko and Johnson

Even assuming, without conceding, that Chanduszko and Johnson are properly combinable, not all the claimed structure or steps of the Applicant's claimed invention are suggested, disclosed, or taught by such a combination.

For example, at least Claim 20 includes structures that engage both ends of a coil implant, unlike the teaching of both Chanduszko and Johnson. Claim 20 recites, in part, "a loading portion releasably engaged with the proximal end of the coil; and a tissue piercing structure releasably engaged with the distal end of the coil, wherein the loading portion holds the coil relative to the tissue piercing structure to axially elongate and radially reduce the coil." As described above, each of Chanduszko and Johnson require only one end of its respective implant to temporarily engage a delivery system, thereby leaving the other end to slide or rotate freely with respect to the delivery system during delivery. Engaging both ends of the implant described by either of Chanduszko and Johnson defeats the purpose and functionality of the respective devices and methods.

In contrast to the combination of Chanduszko and Johnson, Applicant's Claim 12 recites, in part, "releasably engaging a plurality of discrete implantable coils with a single delivery device, the single delivery device comprising a tissue piercing structure, the plurality of discrete implantable coils comprising a distal most coil releasably engaging the tissue piercing structure and one or more proximal coils positioned axially along the single delivery device." The Office Action states at page 4 that "additional coils may also be inserted into other portions of the tissue as seen in Figures 24-25." Note, however, that these figures from Johnson merely reflect steps in delivering a single grommet 100 to the body:



Johnson states "As described above, additional grommets 100 are inserted into the first and second portions of bone of the patient, and the first and second portions brought together and secured." Johnson col. 19, lines 41-44. Johnson only describes delivering one grommet 100 at a time. Johnson does not disclose "releasably engaging a plurality of discrete implantable coils with a single delivery device, the single delivery device comprising a tissue piercing structure, the plurality of discrete implantable coils comprising a distal most coil releasably engaging the tissue piercing structure and one or more proximal coils positioned axially along the single delivery device." The Office Action has failed to explain *why* one skilled in the art would have found it obvious to use a plurality of coils, and has not provided any evidence supporting the obviousness finding, either in another reference or based on the knowledge or common sense of one having ordinary skill in the art.² In light of the prior art limiting itself to the use of a single coil, it would not have been obvious to use a plurality of coils to close a PFO.

Claim 12 also recites "retracting the tissue piercing structure proximally to engage an additional coil without removing the tissue piercing structure from the body of the patient." Again, the Office Action's cited combination does not suggest how, upon retracting the tissue piercing structure, an additional coil would be engaged with the tissue piercing structure without removing the tissue piercing structure from the body of the patient. Accordingly, Applicant submits that Claim 12 is allowable over the combination of Chanduszko in view of Johnson.

² 72 Fed. Reg. at 57528 ("The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.").

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Therefore, for at least the reasons set forth above, Applicant submits that Chanduszko in view of Johnson does not render Claims 5, 12, 20, or any claims depending from these claims, obvious. The foregoing references, when viewed alone or in combination, do not disclose, teach, or suggest each and every element of the claimed invention.

C. Dependent Claims 2-11, 13-15, 17-19, 21-25, 27-30 and 32 Recite A Unique Combination of Features Not Taught or Suggested by the Cited Art

The outstanding Office Action rejected dependent Claims 2-11 under 35 U.S.C. §103(a) as being unpatentable over Chanduszko in view of Johnson. Claims 2-11 depend from Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1, as well as the lack of any explained rationale to combine Chanduszko in view of Johnson, Applicant respectfully submits that Claims 2-11 are patentable over Chanduszko in view of Johnson. Claims 2-11 are also patentable over Chanduszko in view of Johnson because of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 2-11 based on Chanduszko in view of Johnson.

The Office Action also rejected dependent Claims 13-15 and 17-19 under § 103(a) as being unpatentable over Chanduszko in view of Johnson. Claims 13-15 and 17-19 depend from Claim 12 and further define the invention of Claim 12. For at least the reasons set forth above with respect to Claim 12, Applicant respectfully submits that Claims 13-15 and 17-19 are patentable over Chanduszko in view of Johnson. Claims 13-15 and 17-19 are also patentable over Chanduszko in view of Johnson because of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 13-15 and 17-19 based on Chanduszko in view of Johnson.

The Office Action also rejected dependent Claims 21-25 and 27-30 under § 103(a) as being unpatentable over Chanduszko in view of Johnson. Claims 21-25 and 27-30 depend from Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submits that Claims 21-25 and 27-30 are patentable over Chanduszko in view of Johnson. Claims 21-25 and 27-30 are also patentable over Chanduszko in view of Johnson because of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 21-25 and 27-30 based on Chanduszko in view of Johnson.

The Office Action further rejected dependent Claim 32 under § 103(a) as being unpatentable over Chanduszko in view of Johnson. Claim 32 depends from Claim 31 and further define the invention of Claim 31. For at least the reasons set forth above with respect to Claim 31, Applicant respectfully submits that Claim 32 is patentable over Chanduszko in view of Johnson. Claim 32 is also patentable over Chanduszko in view of Johnson because of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claim 32 based on Chanduszko in view of Johnson.

D. Dependent Claims 27 and 33-35 Recite A Unique Combination of Features Not Taught or Suggested by the Cited Art

The outstanding Office Action rejected dependent Claims 27 and 33-35 under 35 U.S.C. § 103(a) as unpatentable over Chanduszko in view of Johnson in further view of Kay. The necessary implication from this rejection is that Chanduszko and Johnson are properly combinable—Applicant respectfully disagrees. Claim 27 depends from Independent Claim 20 and further defines the invention of Claim 20. Claims 33-35 depend from Independent Claim 31 and further define the invention of Claim 31. For at least the reasons set forth above with respect to Claim 20 and Claim 31, as well as for patentable aspects recited within each dependent claim, as well as the lack of any explained rationale to combine Chanduszko in view of Johnson, Applicant respectfully submits that Claims 27 and 33-35 are patentable over Chanduszko in view of Johnson. As explained above in Part I.B.1, Chanduszko and Johnson are not properly combinable. Without completely revisiting that argument, the essential point is that Chanduszko would be inoperable for its intended purpose if modified as suggested by the Examiner.

Moreover, with respect to Claims 33-35, none of Chanduszko, Johnson or Kay, alone or in combination, teaches or suggests a delivery device comprising “a loading collar provided over the tissue piercing structure that is rotatable and axially moveable relative to the tissue piercing structure, the loading collar releasably engaging the proximal end of the coil while the tissue piercing structure releasably engages the distal end of the coil to hold the coil in the axially stretched and radially compressed configuration.” The Examiner provides no explanation for how the alleged loading collar of Kay could be adapted to the combined invention of Chanduszko and Johnson, let alone a loading collar provided “over the tissue piercing structure”

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as claimed. Applicant submits that there would be no reasonable expectation of success to make such a combination.

Thus, for at least the reasons set forth in that part of this response, Applicant respectfully submits that Claims 27 and 33-35 are patentable over Chanduszko in view of Johnson in further view of Kay.

III. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

IV. Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

| Serial Number | Title | Filed | Matter Reference |
|----------------------|---|--------------|-------------------------|
| 11/607237 | TISSUE OPENING OCCLUDER | 11/30/2006 | EV3.062DV2 |
| 11/927448 | TISSUE OPENING OCCLUDER | 10/29/2007 | EV3.062C1 |
| 10/419412 | SEPTAL DEFECT OCCLUDER | 4/21/2003 | EV3.058CPC1 |
| 12/356506 | DEFECT OCCLUDER RELEASE ASSEMBLY & METHOD | 1/20/09 | EV3.059C2 |
| 12/110186 | RETRIEVABLE SEPTAL DEFECT CLOSURE DEVICE | 4/25/2008 | EV3.067C1C1 |
| 10/972635 | PATENT FORAMEN OVALE CLOSURE SYSTEM | 10/25/2004 | EV3.079A |

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| 10/771845 | PATENT FORAMEN OVALE CLOSURE SYSTEM | 2/4/2004 | MVMDINC.019A |
| 10/783783 | DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE WITH A COIL-SHAPED CLOSURE DEVICE | 2/20/2004 | MVMDINC.060A |
| 10/841880 | DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE USING A COUNTERTRACTION ELEMENT | 5/7/2004 | MVMDINC.068A |

V. **Conclusion**

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, she is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 7-22-09

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